EXHIBIT D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF BRIAN RAYBON, MD
PROLIFT +M

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure.

QUALIFICATIONS

I am Board Certified in both Ob/Gyn and Female Pelvic Medicine and Reconstructive Surgery. I obtained a BA in Chemistry and a BS in Chemical Engineering from North Carolina State University. I attended medical school at the University of North Carolina and then did a four year residency in Gynecology and Obstetrics at Emory University. After completing my residency, I spent a year overseas participating in visiting fellowships in different countries where the focus was on both pelvic surgery and gynecologic oncology. Upon returning to the United States, I completed a fellowship in Pelvic Surgery at the Institute for Special Pelvic Surgery in Baltimore, Maryland. Since then, I have been in private practice in North Georgia. Most recently, I am participating as a Core Faculty Member helping to develop a residency program at Athens Regional Medical Center in Athens, Georgia. This program will be the first

new residency program in Georgia in over two decades. In addition, last year I was appointed Clinical Assistant Professor at the Medical College of Georgia.

Since the early 2000s I have been a consultant, preceptor and proctor for various companies including: CR Bard, American Medical Systems, Coloplast and Medtronic. I had an extensive relationship with CR Bard where I was involved in the early developmental stages of the Avaulta prolapse mesh product lines, as well as the Align and Ajust urethral slings.

I implanted over 300 of the Avaulta POP mesh kits, which are similar in design and implantation method to Gynecare"s Prolift devices. I have also evaluated and used other pelvic mesh devices. I implanted over 25 Prolift products. I stopped using the Prolift products in 2008 due to an unacceptably high erosion rate and personal knowledge of the fact that Gynecare did not exercise due diligence in insuring that implanting physicians were adequately trained. In the years since, I have removed over 75 of the Prolift products.

Based upon my work as an urogynecologist and pelvic floor surgeon, I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis, and treatment of patients suffering from complications caused by pelvic mesh implants. The most common mesh related complications include pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve damage.

OPINIONS

All of my opinions in this report I hold to a reasonable degree of medical certainty.

A. The Prolift +M was defectively designed and its risks outweighed any benefits.

The Prolift +M was different from previous Ethicon/Gynecare pelvic mesh devices. It was made of Ultrapro, a mesh sold by Ethicon for hernia repair. Ultrapro mesh was a weave of both larger pore polypropylene and absorbable Monocryl. The Monocryl was supposed to be absorbed in about 90 days, leaving the polypropylene mesh to support prolapsed pelvic organs. The mesh was shaped similarly to Gynecare"s Prolift, except that its posterior straps (or arms) were straight, not curved.

Because this was a new and different prolapse repair mesh, I was interested in reading pre-launch study results, as internal documents suggested the need for such in order to determine whether the new design and the Ultrapro concept would be compatible in the female pelvis when implanted transvaginally with trocars and cannulas in the female pelvis. The European Medical Director for Ethicon recognized the lack of data for this new pelvic organ repair mesh, and the fact that animal studies and pre-clinical trials were needed.[1] In 2006, Ethicon met with Dr. Jan Deprest to discuss the introduction of Ultrapro mesh for urogynecological use, recognizing that "[t]here are no data on physical and morphological outcome following vaginal implantation," and, regarding clinical studies, suggested that such studies "include, if possible, „vaginal" measures, such as…in vivo elasticity, post harvesting elasticity. Also, regular inspection and documentation of the wound healing process might be interesting."[2]

A few months later, Dr. Arnaud learned that Ethicon was proceeding toward the use of Ultrapro in the female pelvis without preclinical or clinical studies, and cautioned that he "was a bit frightened to see that we are currently building a full business story on that, not having yet validated the proof of concept, neither from animal experiments nor from clinical use,"… "a logical way to proceed would be" to first study the mesh in animals, then move to clinical trials

and perform an observational study, and then discuss the need for a formal randomized controlled trial to compare Ultrapro to other Ethicon pelvic prolapse mesh products.[3]

Ethicon canceled a study by Dr. Deprest that it had sponsored and suggested that hernia mesh literature relating to Ultrapro had made the study unnecessary.[4] Dr. Deprest replied: "The animal study you actually agreed to… had (a) different goal(s)...I am afraid there is something else here I should now [sic]."[5] Dr. Deprest further stated that "[t]his animal work seemed to be a critical step prior to do clinical studies," and that his animal studies were intended to "give important new information (the vaginal part, in particular elasticity), as well as the control of data in the abdominal wall, which is the reference."[6]

Ethicon personnel recognized the lack of safety and efficacy data available for the Prolift +M.[7]

After the Prolift +M was on the market, Dr. Vincent Lucente, a key Ethicon consultant, was asked during an Ethicon webinar whether there were any patients in whom he would not use Prolift +M. He replied: "I would say I would go back to PROLIFT in general. Because until we have a harder science on PROLIFT M, I wouldn't want to oversell and underdeliver."[8]

Ethicon's documents reflect that the particular weave of the Ultrapro mesh used in the Prolift +M kit was susceptible to elongation, which led to the "ropes in the longitudinal direction when stretched" which could increase the anatomical failure rate and that the design had an "unacceptable 45% narrowing."[9]

Internal documents reveal concerns that no Ethicon pelvic repair mesh (including the mesh used in Prolift +M) was designed for use in the female pelvis, and the serious problems associated with incompatibility in this unique anatomical region. Ethicon's Worldwide Marketing Director wanted to market the Prolift +M mesh in patient brochures as a "specifically

designed synthetic material." But Ethicon"s Risk Manager responded: "This mesh was not 'specifically designed' for Prolift application, we pulled a mesh out of our existing bag of tricks. This statement is unsupportable form (sic) a design history standpoint."[10] Even after Prolift +M was made available for sale, Ethicon"s internal documents continue to acknowledge that the mesh used in the Prolift +M was not designed for use in the female pelvis, was not ideal for such use, and that the company needed a better alternative.[11]

As it turned out, the safety and efficacy of the Prolift +M was not established when clinical study data did become available.

In February 2010, results "demonstrate[d] an anatomical success rate in the treated compartment of 78.3%...after 12 months, thereby failing to meet its primary endpoint."[12] The study showed an erosion rate of 10.2%, incidences of de novo pelvic pain, vaginal wall stiffness, worsening or de novo stress urinary incontinence, and "contracted firm mesh palpable to right lateral wall at level of anterior arm…Rim of mesh palpable on anterior wall at level of posterior arms."[13]

As it progressed through the development stage, Prolift +M was known as the Lightning Project. It was known during development that the arms of the mesh device were problematic (as was also true with the predecessor Prolift kit). As Dr. Arnaud (Medical Affairs Director – Europe, Middle East and Africa) raised in December 2006, many of Ethicon"s physician consultants "believes that the retraction of the arms are playing a key role in so-called „mesh shrinkage". This is particularly true for the deep anterior arms which can create a kind of cord reducing the depth of the vagina in particular when a hysterectomy has been performed…they believe the arms are needed for the immediate stabilization of the prostheses but are source of

troubles after it has been achieved. Thus, they believe a mesh with absorbable arms could be an interesting concept to consider."[14]

Three-year Prolift +M clinical study reported anatomical success of 75.9% and a mesh exposure rate of 14.8%.[15]

The risks inherent in the design of the Prolift outweigh its benefits for several reasons, including but not limited to:

1. The Gynecare Prolift +M systems require transvaginal implantation of a synthetic polypropylene mesh using specially designed trocars (needles) and sleeves. These products are comprised of a main mesh area and arms which act as fixation points to anchor the mesh arms in the obturator internus, levator ani muscles, and/or the sacrospinous-coccygeus complexes bilaterally. The Prolift +M products consist of a central portion with arms for anchoring the mesh in the pelvic sidewall, and were sold as separate systems intended for the independent treatment of anterior and posterior prolapse, with arms for anchoring the mesh in the pelvic sidewalls, 4 arms for the anterior portion, and 2 arms for the posterior portion. The arms are passed through the sacrocpinous-coccygeus complex proximally and through the obturator foramen, near the junction of the superior and inferior pubic rami, distally. The products are implanted by blindly passing trocars inward through the perineal skin, obturator foramen, obturator internus, levator ani or sacrospinous-coccygeus complex, out through a mid-vaginal incision, then withdrawing the trocars and leaving the plastic sleeves in place. A noose is then passed through each sleeve, and brought into the midvaginal incision. Then, the mesh arms are placed into the loop of each noose, which is then pulled to bring each mesh arm outward into place, thereby anchoring the mid portion of the mesh either between the bladder and anterior vaginal wall (anterior Prolift +M), or between the rectum and the posterior vaginal wall

(posterior Prolift +M). As the Prolift +M mesh arms are being pulled through the plastic sleeves, they conform to the shape of the small bore cylindrical sleeves, which causes deformation and curling of the arms, altering the shape of the arms at the point of contact with the pelvic sidewall. The arms are composed of synthetic polypropylene mesh, and they are intended to scar into place at the muscle attachment points for each arm. For the Prolift +M products, there will be arms in the left pelvic sidewall muscles (the sacrospinous-coccygeus complex proximally, and the obturator internus and levator ani distally) and in the right pelvic sidewall muscles. In this way, the main body of the Prolift +M mesh is intended to support the anterior and posterior walls of the vagina, to correct anterior and/or posterior prolapse, respectively. Polypropylene mesh is known to cause tissue contraction (referred to as mesh shrinkage). When the mesh shrinks, the arms of the mesh pull on their anchoring points in the pelvic sidewall muscles (obturator and levator ani), tending to pull these anchoring points and the attached muscle toward the midline. It is my opinion that, in women with these Prolift +M transvaginal mesh implants, this pulling on the pelvic sidewall muscles causes pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping, and straining. These arms along with the scar plate that can occur around the body of the mesh turn the vagina into an immobile organ which it is designed to be anything but. Attempts at defecation or sexual penetration will push on the mesh, aggravating the pulling on the arms as stool attempts to come out of the rectum, or as the penis is placed into the vagina during intercourse. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. Furthermore, this "side –to-side" surgical approach attempts to address apical (upper end of the vagina) prolapse that may be present by anchoring the mesh arms bilaterally through the sacrospinous-coccygeus complex. However, this bilateral anchoring creates a nonexpandable "spanning" bridge over the rectum

which has the potential to obstruct stool passage and cause pain. I have seen several patients present "acutely" with this problem and treated initially for a bowel obstruction, and then I was consulted for management of this "distal" obstruction. During coughing, jumping, or straining, pressure is placed on the mesh, which is transmitted to the attachments in the pelvic sidewall, also deforming and pulling on the muscle at the attachment points.

The mechanical stresses imposed by the side to side attachment via the arms in combination with the shrinkage by the mesh cause patients pain. Scar plate formation also causes pain. I have surgically removed transvaginally placed meshes from women who had complications related to previously placed Prolift +M transvaginal meshes. I have personally observed shrunken, scarred explanted tissue and deformed Prolift +M mesh remnants as I have attempted to surgically remove the products. Sometimes the scarring and retraction is so severe that the mesh forms a crumpled ball.

The vagina is not a static organ. It functions as a support device; it stretches to accommodate varied functions such as childbirth, intercourse, defecation and urination. The mesh is static and does not "give" according to the needs of the tissues in which it is implanted. Additionally, the fibrotic shrinkage further restricts the functional mobility of the pelvic floor organs and restricts the natural movements of the vagina during defecation, urination, and intercourse. These conditions cause pain.

2. The polypropylene material used in the manufacture of the mesh used in the Prolift +M devices was known to cause an intense and chronic foreign body reaction and inflammation, was prone to shrinkage, and was known to be subject to degradation inside the body.[16] Published medical and scientific literature available to Ethicon revealed that the mesh was not inert and was subject to degradation inside the body, and that this degradation has

adverse medical consequences.[17] It is my belief that this degradation is an ongoing process that can cause clinical issues years down the road remote from the initial implantation.

3. The mesh arms of the Prolift +M were placed through a rounded cannula trocar tunnel that had a diameter smaller than the mesh was wide. The trocar-based insertion of mesh arms causes the arms to deform, fold, curl and/or roll, which causes or contributes to the excessive scarification and contraction of the arms. These mesh arms also deform (cord, rope) upon implantation and after implantation when forces are exerted on the central portion of the mesh and pull on the arms. I have never removed Prolift +M mesh arms that were not severely deformed. The deformation of the mesh arms impedes the body"s ability to incorporate into the material, and contributes to the excessive fibrotic reaction, scarification and shrinkage and pain. The arms themselves, scarred into muscle and other tissue, can exacerbate inflammation, entrap nerves, and cause pain.

4. As the Prolift mesh scars in, the resulting shrinkage or contracture of the tissues surrounding the mesh can entrap nerves, deform the vagina and pelvic anatomy, and result in severe, permanent and difficult-to-treat or untreatable pain as a result of the chronic inflammatory response and fibrosis.[18]

5. The blind passage of the metal trocars during implantation is dangerous and risks tissue damage, vascular damage, nerve damage, and internal trauma.[19] While this risk can be ameliorated in the hands of an experienced surgeon with an in-depth knowledge of female pelvic anatomy, too often this was not the surgeon Ethicon chose to work with.

6. The pelvic floor needs to be supple and flexible to perform its many functions, and to accommodate movement and forces associated with activities of daily living. Literature on hernia mesh has reported that mesh can cause "considerable restriction of abdominal wall

mobility" and "rigidity and discomfort, especially at the edge of the mesh, are frequently reported complaints."[20] Since it was known from published literature that mesh can be or become rigid and restrictive, Ethicon should not have used this material in the vagina, which has much greater sensitivity and requires far greater flexibility than the abdomen.

In March 2010, Ethicon decided that a product in development, T-Pro, would "no longer have the Prolift instruments and procedure" and that "the shape of the graft has to change for obvious reasons, i.e., a new trocar-less delivery system and new procedure…" In response, Ethicon"s Worldwide Marketing Director admitted that "T-Pro is the first ever PFR graft designed for pelvic surgery…First time a graft has been designed to match the dynamic of the vagina especially site specific flexibility….First time a graft has been designed to match the requirements of wound healing especially resistance to wound contracture." (HMESH_ETH_02328102-4).

7. The Prolift +M is implanted through a transvaginal approach, which means the mesh goes through the vagina. Large amounts of bacteria are present in the vagina and can attach to the mesh, where the bacteria can proliferate, and result in abscesses, fistulae, infection, and chronic or permanent inflammation.[21]

8. The polypropylene component of the Ultrapro mesh used in the Prolift+M kit was known to cause an intense and chronic foreign body reaction and inflammation, and was prone to shrinkage.[22] Other materials were available to Ethicon for use in the Prolift+M which were no less effective and which were safer than polypropylene.[23]

9. The mesh in the Prolift+M was not designed for use in the female pelvis.[24]

10. The Monocryl in the mesh used in the Prolift +M caused increased inflammation.[25]

11. It is difficult to completely remove a mesh implant like the Prolift+M. Surgery to attempt to remove mesh comes with its own complications.

B. Ethicon had at its disposal a number of safer feasible alternative designs that count have been utilized.

Aside from the use of native tissue repairs, or non-surgical pelvic organ prolapse treatment like Kegel exercises and pessaries, there were several alternatives to the design of the Prolift kits that would have been safer and just as effective if not more effective. Some of these alternatives include, but are not limited to: elimination of the permanent mesh arms;[26] elimination of the armed, blind trocar passes; introduction of stress shielding to prevent pore collapse, mesh folding, and mesh deformation;[27] and/or used of alternative materials, such as biologic materials or polyvinylidene fluoride (PVDF/Pronova), which Ethicon recognized as safer than polypropylene.[28] Ethicon has developed and/or sold products that contain some or all of these safer design components and/or characteristics, leaving no question that it was feasible for Ethicon to develop a safer design. In fact, Ethicon internal documentation notes that compared to polypropylene, Pronova is "easier to manufacture and sterilize."[29]

C. Ethicon failed to adequately warn physicians and patients about known problems with the Prolift +M.

I have reviewed and am familiar with the Instructions for Use, Physician Training materials, and sales and marketing materials generated by Ethicon for the Prolift +M. I have also reviewed the IFUs for many other medical products that I have implanted and explanted in patients during the many years I have been practicing urogynecology and pelvic reconstructive surgery.

The IFU is a document which physicians reasonably rely upon to make informed decisions about whether and how to use a medical device. The contents of the IFU should assist the physician in an analysis that is employed when determining whether to recommend a particular product as a surgical option to a patient. I have read the IFUs for the Prolift +M products.

In order to make an informed decision as to whether to use a particular product in a given patient, a reasonable physician would expect a medical device company to provide relevant information known to the company that could impact the physician"s decision to use that product. Failure of the company to provide relevant information in its possession bearing on the potential safety of a product prevents physicians from making an intelligent decision regarding whether to implant the product. It also prevents physicians from properly counseling patients in considering whether to consent to surgery for permanent implantation of the medical device.

In making an informed decision of whether or not to use a medical implant, the physician must be warned not only of the potential adverse events that may be associated with the product, but also their frequency, severity and potential duration. Providing informed consent to my patients is a responsibility I take very seriously, as do most physicians. If a medical device company knows that the specific design of its product causes or increases the risk of a complication, the manufacturer is, in effect, minimizing the risk by misinforming doctors that the risks associated with the product "are those typically associated with surgically implantable materials," as stated in the IFU for the Prolift +M. If a manufacturer knows that a complication can be chronic, severe or permanent, it should provide that information to those using its products.

Ethicon did not warn physicians or patients that the straps or arms would roll and rope and curl. The roping of the arms can result in "banding", which leads to pain.[30] The risks of painful shrinkage, scarification and contraction of the mesh arms were not included in any warning.[31]

If Ethicon knew or had reason to believe that the Prolift +M could not be safely used in specific patients (such as those with diabetes or fibromyalgia), the IFU should have provided a warning regarding use in those patients.

The IFU states that "[a]nimal studies have shown that Gynemesh M mesh elicits a minimum to mild foreign body reaction, which is followed by collagen tissue ingrowth through the mesh, thus incorporating the mesh into adjacent tissue." But Ethicon"s information showed that the Prolift +M polypropylene caused an "excessive" and "chronic" foreign body reaction and "intense" and "chronic" inflammation.[32]

The IFU representation that "[t]he mesh remains soft and pliable and wound healing is not noticeably impaired" is not supported. Ethicon"s documents show the polypropylene material was known to be stiff and inflexible, too strong for the pelvis, and was not designed for the pelvic floor.[33]

The affirmative representation contained in the IFU that the polypropylene portion of the Prolift +M mesh was not subject to degradation is refuted by internal documents which say that the polypropylene was subject to degradation.[34]

Ethicon failed to completely and adequately warn physicians and patients about significant risks associated with the Prolift +M.

There was no warning that the polypropylene in the Prolift +M device causes enhanced and persistent inflammation and foreign body reaction, and is susceptible to degradation, and

there was no warning that the absorbable Monocryl in the Prolift +M would also cause or contribute to the enhanced inflammation and foreign body reaction.[35]

There was no indication that women with higher grade prolapse were "better suited" for the Prolift +M then those with milder prolapse.[36]

The Prolift +M IFU generically listed "pain," "pelvic pain, which may resolve with time," and "dyspareunia, which may resolve with time" in the "Adverse Events" section, but then states that these complications "are those typically associated with surgically implantable materials." Adding this limiting language nullified the effectiveness of this warning.

There was no warning of the potential for painful mesh shrinkage that can be chronic or permanent, and difficult, if not impossible to treat.

There was no warning that the use of mesh through a vaginal approach can lead to complications and tissue retraction which can result in anatomical distortion of the vaginal cavity that can interfere with sexual intercourse, or that this complication was increased when there was an associated hysterectomy, or that this risk must be taken into consideration when the procedure is planned in a sexually active woman.[37]

There was no warning that some complications may require additional surgery that may not correct the complication, and that one of the serious potential complications, because of its effect on quality of life, was scarring and narrowing of the vaginal wall.[38]

There was no warning regarding the heightened risks of nerve damage and entrapment caused by the Prolift+M mesh after implantation.[39] Although the Prolift +M IFU lists "injury, nerve," there is limiting language that this complication is "typically associated with surgically implantable materials." This language gave no indication to doctors or patients that the mesh

itself can damage nerves as it scars in and contracts over time, or that this can be difficult to treat and may be permanent.

There was no warning of the difficulty of surgically extracting the Prolift+M mesh.

Surgeons such as myself cannot weigh the risks and benefits of a medical implant or provide adequate information to the patients unless they are aware of all of the information known to the manufacturer that could affect the safety and efficacy of the implant. Ethicon should have had such relevant information at the time of the products" launch. But if not, once such information became available, the company should have supplemented it"s IFU so that surgeons could properly advise their patients about the dangers associated with the implant.

D. Clinical Trials Demonstrated to Ethicon That Functional Outcomes Are Not Superior With Transvaginally Placed Armed Mesh (TVM)

I have participated in clinical trials.

When successful prolapse repair surgery is defined to include functional outcomes, the risk of TVM surgery is greater than the benefit. "Transvaginal mesh has a higher re-operation rate than native tissue repair" due to the rate of surgeries for attempted repair of mesh complications.[40] Also, there is no functional or anatomic benefit for TVM use in the posterior compartment.[41] While TVM may offer improved anatomical outcomes for polypropylene mesh compared to anterior colporrhaphy, this does not translate into improved functional outcomes or a lower reoperation rate for prolapse, and TVM increases morbidity.[42],[43]

Prolift+M had "an anatomical success rate in the treated compartment of 78.3%...after 12 months, thereby failing to meet its primary endpoint."[44] Prolift +M was also associated with incidences of de novo pelvic pain, vaginal wall stiffness, worsening or de novo stress urinary incontinence, and contracted firm mesh at the level of the anterior and posterior arms.

After 3 years, anatomical success was 75.9% and mesh exposure was observed in 14.8% of patients."[45]

I have studied the peer-reviewed urogynecological articles, participated in urogynecological clinical studies, reviewed Ethicon"s internal documents and testimony, and surgically removed Prolift +M mesh. Based thereon, it is my opinion that use of the Prolift +M implant far outweighed its perceived benefits, and resulted in unacceptable rates of mesh exposures, erosions, dyspareunia, chronic pelvic pain, surgeries to address these complications, and occurrences of prolapse following such surgeries.

E. General causation opinions

I have personally observed and treated patients who have been implanted with Ethicon Prolift+M products that experienced the following device-related complications:

1. Chronic or permanent pelvic pain;
2. Chronic or permanent inflammation of tissue surrounding the mesh;
3. Excessive scar plate formation, scar banding, and contracture of mesh arms, resulting in asymmetrical pulling on the central portion, causing pain;
4. Erosion of mesh into the bladder or rectum and exposure of mesh in the vagina;
5. Pudendal neuralgia;
6. Pelvic floor muscle spasm;
7. Nerve injury/damage and direct trauma to organs and tissues caused by the blind passage of trocars;
8. Nerve damage or nerve entrapment as a result of mesh scarification and fibrotic bridging;
9. Dyspareunia;

10. Stress urinary incontinence and urge incontinence;

11. Urinary retention;

12. Constipation or fecal incontinence;

13. Deformed, wrinkled, folded, curled, roped, and fragmented mesh upon removal;

14. Encapsulation of mesh (mesh covered in thick scar);

15. Vaginal shortening, tightening, stenosis and/or other deformation of the pelvic anatomy;

16. Infection, including bladder infections, vaginal infections, chronic urinary tract infections, and abscesses;

17. Fistulae; and

18. Recurrence of prolapse (failure of treatment).

Medical literature also discusses these complications with other transvaginal pelvic organ prolapse repair implants.[46]

Based upon my education, training, experience and knowledge, and my familiarity with the literature relating to this subject, it is my professional opinion to a reasonable degree of medical certainty that the injuries and complications that I have personally observed, diagnosed, and treated relating to the Prolift+M are directly attributable to the defective design of this product as described previously. It is also my opinion that many if not all of these complications could have been prevented had Ethicon used safer feasible alternative s to the implant's design or had completely and adequately instructed surgeons and warned surgeons and patients of significant known risks associated the implant.

DATA CONSIDERED IN FORMING MY OPINIONS

I considered the documents identified in the body and footnotes of this report, as well as those listed in Exhibit B attached hereto.

EXHIBITS WHICH I PLAN TO USE AS A SUMMARY OF OR IN SUPPORT OF MY OPINIONS

Exhibits which I plan to use as a summary of or in support of my opinions are as follows:

- Exhibits extracted from the materials that I have reviewed specific to this case (as described in references and/or footnotes contained within this report and referenced herein at Exhibit "B");
- Excerpts from medical articles and learned treatises and textbooks;
- Examples and/or exemplars of the Prolift +M product(s);

COMPENSATION FOR MY REVIEW, STUDY AND TESTIMONY

For case review, consultation, and conference calls: $500/hr in 15 min increments

For trial testimony, $4,000/half day and $8,000/half day in 4 hour increments

For deposition, $600/hour with a minimum of a 4 hour charge

For travel time, $200/hour in 30 min increments plus expenses

Full payment for cancellation/rescheduling within 2 weeks

50% payment for cancellation/rescheduling within 4 weeks

OTHER CASES IN WHICH I HAVE TESTIFIED AS AN EXPERT AT TRIAL OR BY DEPOSITION IN THE LAST FOUR YEARS

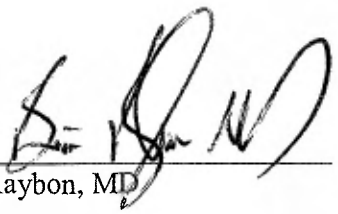
A list of other cases in which I have testified as an expert at trial or by deposition within the preceding four years is as follows:

Cisson v. C.R. Bard

Dotres v. Boston Scientific

State v. _____ (rape case)

Mary Catherine Wise v. Ethicon - deposition



Brian Raybon, MD

CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2016, I served the **PLAINTIFFS' RULE 26(a)(2)(B) EXPERT REPORT OF BRIAN RAYBON, M.D.** on the following counsel of record by electronic mail:

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[1] ETH.MESH.03915690 (5/13/05 internal e-mail "Use of ULTRAPRO Mesh for Pelvic Organ Prolapse").

[2] HMESH_ETH_00602957 (8/21/06 report "Decision on Proposal from Dr. Deprest").

[3] ETH.MESH.03160750 (11/15/06 internal e-mail from Ethicon European Medical Director to Ethicon's Medical Director).

[4] ETH.MESH.05242095 (12/21/06 e-mail between Dr. Deprest and Ethicon's Peter Meier).

[5] Id.

[6] Id.

[7] ETH.MESH.14429052 (12/3/08 Ethicon PowerPoint presentation), pp. 12-13.

[8] ETH.MESH.00067354 (12/15/08 "Q&A transcription").

[9] ETH.MESH.02599391 (8/20/10 internal memo "Memo to Elongation of Gynmesh M) – "[T]he mesh has different elongation in longitudinal and transversal direction."; "If, however, it would turn out that the added elasticity of the mesh contributes to further relaxation and anatomical features, the horizontal placement of the mesh may no longer be advisable." (p. 9393); "[I]n the company sponsored trial on Prolift+M we have observed a relaxation of the vaginal walls between the 3 and 12 month time period, leading to a slight decrease of the anatomical success rate." (Id.); "Whether horizontal placement may lead to more anatomical failures of apical support cannot be determined from the current evidence…" (Id.); "In conclusion, I would advise not to advocate either directional use in both vaginal or abdominal approaches. The surgeons should be informed of its differential elastic properties." (p. 9394)); ETH.MESH.01785259 (1/17/10 internal e-mail from Ethicon Med. Director "Re: +M relaxation"): "[Klosterhalfen] believes that indeed the mesh will become more elastic after three months as the monocryl component will continue to add extra stiffness until full resorption. He believes this may explain what we observe in the +M series [vaginal wall relaxation]."); ETH.MESH.00579391 (10/15/10 internal e-mail "Lab results of Mesh roping evaluation") – Gynemesh +M lab testing showed mesh ropes in the longitudinal direction when stretched, and Ethicon employee responsible for testing states his desire "to kill the longitudinal design given its unacceptable 45% narrowing," to which Ethicon Med. Director replies "Prof Deprest had been at a meeting challenging that indeed we cut the Prolift +M mesh in the wrong direction.").

[10] ETH.MESH.00126755 (5/8/08 internal e-mail from Ethicon's Worldwide Risk Management Director).

[11] ETH.MESH.02141727 (5/08/08 internal PowerPoint) – "There is still NO evidence of a Device created specifically for the female pelvis." (p. 4); "Pelvic Floor materials are still over-engineered → we need less foreign body material → materials that correlate to measured female

pelvic values." (p. 6)); ETH.MESH.02142351 (8/05/08 internal PowerPoint) – anticipated new mesh design "will be the first PFR device designed specifically for the female pelvis."); ETH.MESH.02142351 (8/25/08 internal PowerPoint), p. 2 – "T-PRO [a new product design, which never went to market] will be the first PFR device designed specifically for the female pelvis."); ETH.MESH.00271215 (10/29/08 internal e-mail) – Polypropylene is "the best of a bad lot re integration/retraction" and "there is a need to develop grafts that mimic the human tissue mechanical properties."); ETH.MESH.09650760 (11/21/08 invention disclosure) – "Mesh based implants which are currently used in pelvic floor reconstruction are based on mesh constructions originally designed for the treatment of hernias in the abdominal wall region. It is important to understand that the biomechanical properties of the abdominal wall and the pelvic floor differ especially in regard of elasticity and anisotropic material behavior. To fulfill the desired biomechanical compatibility of mesh based implants for pelvic floor reconstruction, it is important to take the biomechanical properties of the implantation site into consideration."); ETH.MESH.00751733 (10/22/09 internal PowerPoint), p. 7 – "There is no patient-centric PF material!"; "Different mechanical properties are needed in different area of PF."); ETH.MESH.02227282 (11/14/09 PowerPoint), Slide 3 – "Until now, there is no patient-centric POP repair material!! Pelvic Floor Materials are still over-engineered – we need less foreign body material – materials that correlate to measured female pelvic physiological characteristics."); ETH.MESH.02010834 (2/16/11 internal memo "Biomechanical consideration for Pelvic floor mesh design") – p. 2 ("The ideal mesh for prolaps[e] repair which mimics precisely the biomechanical needs of the pelvic floor region has not been developed.... Pain and discomfort can result from stiff mesh that were originally designed for hernia surgery and „over-engineered" to exceed the burst strength of the abdominal wall at the cost of losing compliance [citing 2009 literature].... [T]here is significant evidence that the complications associated with synthetic meshes can cause significant morbidity including infection, erosion, exposure, and pain [citing 2000 and 2007 literature].... In addition, the vaginal tissue to be augmented in often structurally compromised, atrophic, and devascularized.... Moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain, and poor restoration of the normal properties of the vagina compliance [citing 2009 literature]. Research has demonstrated that bioprosthetic mesh implantation results in a scarring reaction and subsequent decreased compliance [citing 2009 literature]."); ETH.MESH.08315779 (9/25/12 Ethicon internal report), p. 5782 – "[S]ynthetic mesh implants, even the lower mass mesh implants, are significantly stronger than required.").

[12] ETH.MESH.01208013 (2/1/10 internal document "Results +M").

[13] (See the published version, Trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh: 1 year outcomes: Milani AL, Hinoul, P, et al. Prolift +M Investigators. Am J Obstet Gynecol. 2011 Jan; 204(1): 74.e1-8.)

[14] ETH.MESH.03912618.

[15] ETH.MESH.06321602 (4/18/12 internal study report).

[16] ETH.MESH.02247342 (9/26/08 internal PowerPoint "The Journey from Prolift to Prolift +M") ("Polypropylene creates an intense inflammatory response…. The excessive inflammatory reaction to heavyweight Polypropylene tends to form a scar plate around the prosthetic that results in a firm and contracted mesh…."); ETH.MESH.13375497 (10/1/08 internal PowerPoint) – "Issues with Polypropylene Mesh • Excessive foreign body reaction • Chronic inflammation…• Scar plate formation • Stiffness…• „Shrinkage" 20-40%.").

[17] Williams, D.F., Review. Biodegradation of surgical polymers, Journal of Materials Science, Vol. 17, 1233-46 (1982) ("[t]he effects of these degradation processes will naturally vary, but generally there will be a change in average molecular weight, molecular-weight distribution, crystallinity and mechanical properties."); Ali, S.A.M., et al., The Mechanisms of Oxidative Degradation of Biomedical Polymers by Free Radicals, Journal of Applied Polymer Science, Vol. 51, 1389-98 (1994) (explaining that the oxidative process "will augment any tissue injury due to the invading organisms. These highly reactive radicals generated by cellular mechanisms at or near the surface of implanted polymers may contribute to damage of the polymer surface in the same fashion as established polymer degradation reactions by reactive radicals."); Zhong, S.P., et al., Biodeterioration/Biodegradation of Polymeric Medical Devices In Situ, International Biodeterioration & Biodegradation, Vol. 130, 95 (1994) (explaining "vicious cycle" between foreign body response to polymer implant material and degradation, stating "poor compatibility can result in serious tissue response, where different enzymes and active species released from cells can damage the implant profoundly, the degradation products then possibly making the tissue response even worse. Obviously, this is a vicious cycle, which needs to be avoided, as it may result in failure of the device and either morbidity or mortality in the patient."); Costello, C.R., et al., Materials Characterization of Explanted Polypropylene Hernia Meshes, J. of Biomedical Mater. Res. Part B: Applied Biomaterials, Vol. 83B(1), 44-49 (2007) (discussing mechanisms and harmful effects of the degradation of polypropylene inside the body, and concluding that explant analyses were consistent with increased abdominal wall stiffness and patient complaints of chronic pain and restricted mobility); Clave, et. al., Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. IntUrogynecol J 2010 Mar; 21(3):261-70.

[18] ETH.MESH.05631478 (8/16/02 internal e-mail discussing article describing mesh-related nerve injury – ("In the post retrieval study most explants of all patients with chronic pain in their history indicate nerve fibres and fascicles in the interface of the mesh. Today, immunohistochemical stains relieve even the detection of smallest nerve structures which are mainly found in the foreign body granuloma. Due to the nature of the granuloma as a chronic inflammation it may be speculated that these nerve structures are irritated by the inflammation and cause the sensation of pain"); ETH.MESH.05455878 (1/18/03 Ethicon Surgeon Panel meeting notes) – Ethicon surgeon advisor told Ethicon "Some rate of long term risk to humans of…nerve entrapment with chronic pain…often the result of tiny nerves in the granuloma…even if you care for the big nerve you can"t prevent pain."); HMESH_ETH_00343700 (7/6/06 internal document commenting on published article) ("in the authors' postrieval study the involvement of nerve fibers was found in more than 60% of all mesh specimens removed due to chronic pain."); HMESH_ETH_01801001 (10/11/06 internal e-mail re: published article) – "The article highlights that 60% of pain related issues in hernia repair are contributed to disturbance with

nerve."); HMESH_ETH_00144721 (2/11/08 internal e-mail) – "Peripheral nerve irritation following synthetic mesh implantation can be implant-related or procedure-related. Implant-related factors include foreign body tissue reaction, fibrotic tissue response and shrinkage."); ETH.MESH.13375497 (10/1/08 internal PowerPoint) (Regarding mesh-related pain "The tissue reaction at the mesh implant is like a chronic wound, present for years and years after the implantation," and studies of explanted meshes show "Nerve fibers and fascicles in the interface of the mesh…The nerve structures are irritated by the inflammation an cause sensation of pain."); Smith T, et al., Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience from a Referral Center. Female Pelvic Med Reconstr Surg 2013; 19:238-41; Klosterhalfen, et al., The Lightweight and Large Porous Mesh Concept for Hernia Repair. Expert Rev. Med. Devices 2(1) 2005; Castellanas ME et al., Pudendal Neuralgia After Posterior Vaginal Wall Repair with Mesh Kits: An Anatomical Study and Case Series. Journ Minimally Invasive Gynecol 19 (2012) S72.

[19] ETH.MESH.12003000 (1/21/09 literature review) – concluding "The blind passage of the trocars in the TVM procedure could cause injury of the surrounding anatomical structures.").

[20]Junge, Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants; Hernia 2001; 5: 113-118.

[21]Vollebregt, et. al., Bacterial colonization of collagen coated PP vaginal mesh: are additional intraoperative sterility procedures useful? Int. Urogynecol J Pelvic Floor Dysfun. 2009 Nov; 20(11): 1345-51; ETH.MESH.03924600 - (11/10/00 internal memo): "vaginal approach to avoid bacterial environment (the vaginal environment is a notoriously dirty one with abundant bacterial flora; avoidance of bacteria is impossible when employing the vaginal route of application.").

[22] ETH.MESH.13375497 (10/1/08 internal PowerPoint) – "Issues with Polypropylene Mesh • Excessive foreign body reaction • Chronic inflammation…• Scar plate formation • Stiffness…• „Shrinkage" 20-40%.").

[23] HMESH_ETH_02860031 (7/06/07 internal e-mail from Ethicon Research Fellow regarding prior "dog" study) – "I recall the long-term dog study did show some „fibrillation" of PROLENE suture where none was observed for PRONOVA suture. My polymer colleagues tell me that PP has the potential to do this because of its molecular structure."); ETH.MESH.00857704 (2/12/09 internal e-mail regarding development of potential new mesh product constructed of PVDF "Pronova") – "I think we have multiple advantages over +M like:…If we use PRONOVA a more elastic fiber which show less degradation than PP. Better, longer function of Implant."); HMESH_ETH_00228962 (2/17/10 internal e-mail chain discussing polypropylene literature) – "[W]e know from literature that polyester and even polypropylene tend to alter over time in the body…. [H]ow has the general surgery group responded to this [degradation literature]?...[W]e proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard." (HMESH_ETH_00228961)).

[24] ETH.MESH.03904451 (6/06/00 internal memo) – "The in vivo forces and exerted strains on pelvic floor repair during the postoperative period are not known. No studies on this subject were identified through literature search or interviews with experts."); ETH.MESH.05643313 (12/1/00 internal e-mail): "Unfortunately we did not measure the elasticity of endopelvic fascia in our animal studies."); HMESH_ETH_00602957 (8/21/06 internal e-mail) – "There are no data on physical and morphological outcome following vaginal implantation…."); ETH.MESH.02017154 (3/06/07 Minutes from an Ethicon Meeting) "Need to learn more about special anatomic features in vaginal region" and noting that vagina is completely different from abdominal wall.).

[25] ETH.MESH.10597798 (2/2/07 audit report re: hernia mesh studies) "Eighty-four days post-implantation, the increased severity of inflammation was attributed to the increased hydrolysis of the poliglecaprone 25 material."; HMESH_ETH_00597870 (10/5/07 internal email discussing study results) "slightly increased inflammation scores noted at interim time points was attributable to the higher amount of bioabsorbable material in the test vs. control."

[26] ETH.MESH.00857704 (2/12/09 internal e-mail regarding future mesh design advantages) – "Absorbable distal arms that will reduce discomfort like leg pain, buttock irritation, etc."

[27] ETH.MESH.02588172 (1/22/08 internal document) – "Mesh pore size varies under the impact [of] an applied load." Report compared mesh with stress shielding to mesh without stress shielding. States of mesh without stress shielding: "microscopic view: reduced pore size due to collapsed pores." States of mesh with stress shielding: "microscopic view: no change of pore size under load, due to stress shielding strategy"; ETH.MESH.02141727 (5/9/08 internal PowerPoint presentation on future product development) slide 6 – "Stress shielding needed to avoid pore-collapse, deformation and pre-stretch"; ETH.MESH.00857704 (2/12/09 internal email regarding future mesh design advantages) – "Temporary stress shielding of the graft reduces folding, deformation, crumbling.. that lead to erosion, pain, etc."

[28] ETH.MESH.09888188 (10/15/92 internal study report) – "Degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking"; ETH.MESH.05644809 (8/2/01 internal notes) – "Advantages of Pronova • 50% reduced granuloma (Aachen group) • high inertness (like Teflon) • durability • reduced bending stiffness (better flexibility) • elasticity (fiber elasticity contributing 25% to mesh elasticity, rest by construction) • higher purity (only a blend)"; ETH.MESH.05588125 (7/6/07 internal email) – Dr. Dieter Engel: "Pronova has a reduced foreign body reaction compared to Prolene, as shown in several animal studies, and will improve the perceived biocompatibility of our mesh"; ETH.MESH.05878699 (9/13/07 internal study report) – Prof. Klosterhalfen: "Pronova [compared to Prolene] indicates a superior biocompatibility in the crucial early stage of wound healing within the first weeks"; ETH.MESH.15377374 (8/12/09 internal communication to a supplier) – "…PVDF polymers showed acceptable and often improved performance as compared to PP mesh devices. We have previously shared the preclinical biocompatibility studies for PRONOVA suture (report dated June 1998). Similar findings would be expected for a mesh device made from PRONOVA blend materials"; ETH.MESH.03722384 (9/16/09 internal e-mail) Dr. Thomas Divilio: "We're seeing

a lot of work published that indicates that polypropylene produces an ongoing, chronic inflammatory reaction…Might be better off working with something that is less reactive, like PVDF"; ETH.MESH.00857704 (2/12/09 internal e-mail regarding future mesh design advantages) – "If we use PRONOVA a more elastic fiber which shows less degradation than PP. Better, longer function of Implant."

[29] ETH.MESH.00869908 (8/14/07 internal project chart).

[30] ETH.MESH.03911687 (11/25/05 e-mail discussing European physician expressing concerns about Prolift arms) – "[doctor] believes that, after retrieval of the canula, the straps take a rope-like shape which is not optimal in his opinion. He has observed that some patients have discomfort as they can feel the straps with Prolift."); ETH-48281 (3/5/09 internal e-mail) ("[Competing mesh manufacturer] has been talking to doctors about the „banding" effect that occurs with the anterior Prolift… The banding that customers are telling me occurs at the edge of the mesh near the apex. Regardless of how doctors adjust the mesh, there is still a definite ridge or banding that can be vaginally palpated with our anterior mesh."); ETH.MESH.04097128 (May 1, 2009 internal e-mail discussing mesh arm "banding") – "the reported clinical information described a post-operative PROLIFT Mesh arm „banding"…, which led to the mesh recipient"s „discomfort" during sexual intercourse. „Mesh banding" describes tension build up on a given part of the pelvic floor mesh. The tension might have been introduced to the mesh at the time of mesh placement, or tension could have built up on the mesh arm as pelvic tissue incorporation into the mesh progressed. Tissue incorporation into the PROLIFT Mesh is an expected in vivo mesh behavior…."); ETH.MESH.07171404 (9/03/09 internal e-mail regarding alternative design to Prolift arms) – discussing how new mesh design "is fixed in a very different (more „dynamic") way than Prolift (fixed and really pulling on the ligaments and muscles via the arms)", and explaining that new products "offer a similar solution to the shrinkage and curling of the mesh" seen with Prolift.); ETH.MESH.08020093 (2/10/10 internal e-mail) ("many docs still split Prolift when using it, and Prosima might be a better option for those docs. We aren"t seeing the banding (ridge of tissue) from spine to spine that we see with other anterior mesh kits. Probably because we don"t have attachment points….").

[31] ETH.MESH.07237575 (9/19/11 internal e-mail containing Medical Director"s response to inquiry about mesh repair systems without arms) – "Mr. Hinoul explains that the arms were meant to keep the mesh in place, but it appears to be technically (too) difficult for surgeons: often they do not go deep enough, which could result in folding of the mesh and exposure of the arms. That is why other types were developed, also by Ethicon. Mr. Hinoul shows examples the Prolift and Prolift +M meshes. Efforts were made to make the mesh lighter and more absorbable than the Ultrapro mesh for hernia, which was rather stiff. More density of the mesh causes more scars. The mesh itself does not shrink, scar tissue is the problem. This problem is not described in the Patient Information Folder, though it is mentioned under „Pain.""").

[32] ETH.MESH.05455879 (1/18/03 notes from Surgeon Panel Meeting) - "Polypropylene - initial acute inflammation then chronic foreign body reaction….Reaction after 6 years."); ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new

material…."); ETH.MESH.00271215 (10/29/08 internal e-mail) – Polypropylene is "the best of a bad lot re integration/retraction" and "there is a need to develop grafts that mimic the human tissue mechanical properties."); ETH.MESH.00680021 (11/12/08 internal e-mail) – "Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissue. The excessive inflammatory reaction caused by heavyweight meshes tends to form a scar plate around the prosthetic that results in a firm and contracted mesh."); ETH.MESH.03722384 (9/17/09 internal e-mail) – "We're seeing a lot of work published that indicates that polypropylene produces an ongoing, chronic inflammatory reaction…Might be better off working with something that is less reactive, like PVDF."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering.""); ETH.MESH.05237872 (Nov. 3-4, 2010 "Mesh and Textile Summit") – PowerPoint addressing downsides of "old fashioned" (i.e., polypropylene mesh): "Excessive foreign body reaction; Chronic inflammation; Decreased fibrocollagenous ingrowth; Scar plate formation; Shrinkage from bridging fibrosis.").

[33] ETH.MESH.02141727 (5/09/08 internal PowerPoint) – "There is still NO evidence of a Device created specifically for the female pelvis." (p. 4); "Pelvic Floor materials are still over-engineered → we need less foreign body material → materials that correlate to measured female pelvic values." (p. 6)); ETH.MESH.09650760 (11/21/08 invention disclosure) – "Mesh based implants which are currently used in pelvic floor reconstruction are based on mesh constructions originally designed for the treatment of hernias in the abdominal wall region. It is important to understand that the biomechanical properties of the abdominal wall and the pelvic floor differ especially in regard of elasticity and anisotropic material behavior. To fulfill the desired biomechanical compatibility of mesh based implants for pelvic floor reconstruction, it is important to take the biomechanical properties of the implantation site into consideration."); ETH.MESH.02010834 (2/16/11 internal memo "Biomechanical consideration for Pelvic floor mesh design") – p. 2 ("The ideal mesh for prolapse repair which mimics precisely the biomechanical needs of the pelvic floor region has not been developed…. Pain and discomfort can result from stiff mesh that were originally designed for hernia surgery and „over-engineered" to exceed the burst strength of the abdominal wall at the cost of losing compliance [citing 2009 literature]…. [T]here is significant evidence that the complications associated with synthetic meshes can cause significant morbidity including infection, erosion, exposure, and pain [citing 2000 and 2007 literature]….").

[34] ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) – "Prof. Cosson questions if Polypropylene is the best material as fractures are observed in pp [sic] after time."); HMESH_ETH_02860031 (7/06/07 internal e-mail from Ethicon Research Fellow regarding "dog" study) – "I recall the long-term dog study did show some „fibrillation" of PROLENE suture where none was observed for PRONOVA suture. My polymer colleagues tell me that PP has the potential to do this because of its molecular structure."); ETH.MESH.05588123 (7/09/07 internal memo responding to mesh degradation literature) – "There have been a number of anecdotal reports that PP mesh shows some changes in the surface with time. The Aachen group, who has so far collected more than 1000 explanted meshes, showed examples many years

back…. We did different tests in-house with accelerated aging, too, and found microscopic changes in the surface of mesh fibres."); HMESH_ETH_00228962 (2/17/10 internal e-mail chain discussing literature about polypropylene degradation) – "[W]e know from literature that polyester and even polypropylene tend to alter over time in the body…. [H]ow has the general surgery group responded to this [degradation literature]?...[W]e proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard." (HMESH_ETH_00228961)); ETH.MESH.10578304 (1/18/11 Minutes of PA Consulting Group Meeting regarding Mesh Erosion) – "PP meshes degrade over time following implant; this is observed at very high magnification (using electron microscopy) as „fractures" in the surface of the extruded fibres which cause particulates of PP to be produced which can break away from the main fibre."); ETH.MESH.14445346 (1/17/12 PowerPoint), Slide 11 (comparing Polypropylene to PVDF) – "PP – Stress cracking after 2 years of implantation [citing Mary article from 1998]… PP – In vivo degradation of PP [citing Clave article from 2009]."); ETH.MESH.07726993 (3/12/12 Ethicon internal memo in response to article reporting polypropylene mesh degradation) – "In an infected field and/or a site of chronic inflammation, it is not unexpected that there will be an increase in free radicals and other reactive oxygen species. Polymers may be subject to surface degradation by these reactive species, the impact of which has not been clinically assessed.").

[35] ETH.MESH.23958005 (article published 3/2005) "The presence of the absorbable poliglecaprone in Ultrapro mesh may initially create an inflammatory reaction that resolves as this portion of the prosthetic absorbs."); ETH.MESH.10597798 (2/2/07 audit report re: hernia mesh studies) "Eighty-four days post-implantation, the increased severity of inflammation was attributed to the increased hydrolysis of the poliglecaprone 25 material."); HMESH_ETH_00597870 (10/5/07 internal email discussing study results) "slightly increased inflammation scores noted at interim time points was attributable to the higher amount of bioabsorbable material in the test vs. control."

[36] ETH.MESH.00877490 (9/8/05 Prolift Poster Presentation by Michel Cosson) "„We can recommend the use of mesh for prolapse surgery, especially patients with big prolapses, and recurrent prolapses," he said, noting that women with grade 4 prolapse and greater are better suited for mesh surgery than patients with less severe disease.").

[37]ETH.MESH.03928881 (1/11/05 internal e-mail from Ethicon European Medical Director Axel Arnaud).

[38] ETH.MESH.01203957 (11/15/08 PowerPoint), Slide 8.

[39] ETH.MESH.00870466 (6/20/06 notes re: Ethicon Expert Meeting) – "Meshes can cause Nerve damage due to mechanical irritation (mesh bears on nerve)…. Vaginal pain after implantation of meshes is rare, but feared, since there is not real treatment option"); HMESH_ETH_01800994 (10/11/06 internal e-mail chain discussing mesh pain/shrinkage literature) ("The take home message from the article was that chronic pain can be associated with placement of a mesh device…. [The author] continues to point out that neuropathy-related complaints after intraoperative damage of nerve fibers is associated with pain immediately after surgery,

however, the onset of chronic pain as a consequence of the „foreign body reaction" is typically more than one year after the hernia repair. He goes on to point out that patients that reported chronic pain demonstrated nerve fibers and fascicles in the interface of the mesh upon examination upon removal."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering."); ETH.MESH.05479695 (Nov. 3-4, 2010 Mesh and Textile Summit PowerPoint) – "Studies of explanted meshes: • Nerve fibers and fascicles in the interface of mesh • The nerve structures are irritated by the inflammation and cause sensation of pain [citing 2005 article].").

[40] de Tayrac R et al., Complications of POP Surgery and Methods of Prevention, Int. Urogynecol. J. 2013; 24:1859-1872.

[41] Karram M, Maher C, Surgery for Posterior Wall Prolapse. Int. Urogynecol. J. 2013; 24(11): 1835-41.

[42] Maher C, Anterior Vaginal Compartment Surgery. Int. Urogynocol. J. 2013; 24:1291-1802; Ostergard D, Evidence-based Medicine for Polypropylene Mesh Use Compared with Native Tissue Repair. Urology 79: 12-15, 2012.

[43] Gutman et al., Three-Year Outcomes of Vaginal Mesh for Prolapse. Obstet Gynecol 2013; 122:770-7.

[44] ETH.MESH.01208013 (2/1/10 internal document "Results +M").

[45] ETH.MESH.06321602 (4/18/12 internal study report).

[46] Hansen, B., et al., Long-Term Follow-up of Treatment for Synthetic Mesh Complications, Female Pelvic Med & Reconstr Surg 2014, 20:126-130; Barski D, et al., Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair. Surg Technol Int. 2014, 24:217-24.; Shah, et. al., Mesh complications in female pelvic floor repair surgery and their management: A systematic review. Indian J Urol. 2012 Apr; 28(2):129-53; Feiner, B., et al., Vaginal Mesh Contraction: Definition, Clinical Presentation and Management, Obstet Gynecol 2010, 115:325-330.